

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA )

v. )

GENE SVIRSKIY ET AL., )

Defendant. )

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Court No.: 14-cr-10363-RGS-3-9, 11-12

**GOVERNMENT’S OPPOSITION TO DEFENDANTS’  
JOINT MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF  
PATIENT HARM RELATED TO METHYLPREDNISOLONE ACETATE**

The United States of America hereby opposes the remaining defendants’ Joint Motion to Exclude Evidence of Patient Harm Related to Methylprednisolone Acetate (Doc. No. 1461) [hereinafter “the Motion”]. The government has already informed counsel for Defendant Evanosky during the meet-and-confer conference that it did not intend to introduce in the upcoming trial (i) evidence of autopsies (photos and medical examiner testimony) or (ii) testimonies of next-of-kin. The government does, however, intend to introduce evidence of the contamination of the methylprednisolone acetate (“MPA”), and the resulting fungal meningitis outbreak that led to the shutdown of NECC and this criminal case. The government submits that this evidence is admissible and highly probative of the racketeering enterprise that defendants Svirskiy, Leary, Evanosky, Connolly, Carter, and Stepanets are charged with operating along with convicted defendants Barry Cadden and Glenn Chin. Accordingly, the government submits that the defendants’ Motion is without merit, and should be denied.

## **ARGUMENT**

### **I. Evidence of the Three Lots of Contaminated MPA is Admissible in a Trial of the Co-Conspirators.**

NECC was a fraudulent criminal enterprise that produced grossly substandard drugs, including contaminated drugs, expired drugs, untested drugs, falsely mislabeled drugs, and drugs made by an unlicensed pharmacy technician. Defendants Svirskiy, Leary, Evanosky, Connolly, Carter, and Stepanets are charged with conspiring with convicted defendants Cadden and Chin to operate NECC in such a manner. Svirskiy, Leary, Evanosky, and Connolly all participated in making these deficient drugs, while Carter and Stepanets had critical roles in the distribution of these deficient drugs to customers across the nation. NECC's fraudulent production and distribution of all of its substandard drugs, including the contaminated MPA, is admissible evidence in a trial of these co-conspirators, regardless of which pharmacist-conspirator made which specific drugs. See United States v. Mangual-Santiago, 562 F.3d 411, 422 (1st Cir. 2009) (noting that each co-conspirator does not need to know or participate in every aspect of the conspiracy); United States v. Flores-Rivera, 56 F.3d 319, 325 (1st Cir. 1995) (holding that in a trial of a co-conspirator "virtually all the evidence relating to the other conspirators [is] also directly relevant to, and therefore, independently admissible in, the prosecution's case against [the co-conspirator]"). They all are charged with participating in the scheme to defraud NECC's customers.

The fact that the co-conspirators were not responsible for compounding the contaminated MPA does not render evidence relating to the contamination inadmissible. Evidence of the contaminated MPA is directly relevant and independently admissible against the co-conspirators. Moreover, the evidence will demonstrate at trial that the other pharmacist-conspirators working inside NECC's clean room used similar unsafe production practices in compounding their drugs

as Chin did in compounding the MPA. Furthermore, evidence of the contaminated MPA and the resulting patient harm is probative of the materiality of the fraud on NECC's customers. Accordingly, evidence of the three lots of contaminated MPA is admissible at the remaining defendants' trial.

## **II. Evidence of the Fungal Meningitis Outbreak Caused by the Contaminated MPA is Admissible in a Trial of the Co-Conspirators.**

Evidence of the nationwide harm caused by the contaminated MPA is also admissible at the remaining defendants' trial. The First Circuit has long held that "[e]vidence that pertains 'to a chain of events forming the context...and set-up of the crime, helping it to complete the story of the crime on trial...[is admissible in appropriate cases]...where it possess[es] contextual significance.'" United States v. Sabetta, 373 F.3d 75, 83 (1st Cir. 2004) (quoting United States v. Ladd, 885 F.2d 954, 959 (1st Cir. 1989)); see also United States v. Charles, 456 F.3d 249, 256 (1st Cir. 2006) (affirming admissibility of evidence explaining why officers approached the defendant). The court has explained that "[e]vidence is not to be examined in isolation, but in its particular factual setting. Evidence of prior conduct is admissible 'to complete the story of the crime on trial by proving its immediate context of happenings near in time and place.'" United States v. D'Alora, 585 F.2d 16, 20 (1st Cir. 1978) (quoting 2 WEINSTEIN'S EVIDENCE § 404(09), at 404-57 (1975)).

In United States v. Parnell, 32 F. Supp. 3d 1300, 1301 (M.D. Ga. 2014), a factually similar case, the defendants, who were owners of a peanut company, were charged with wire fraud and Food, Drug, and Cosmetic Act ("FDCA") violations for the shipment of contaminated peanuts to distributors around the country. The contaminated peanuts led to a salmonella outbreak that sickened and killed many consumers. Prior to trial, the defendants moved to exclude evidence of the salmonella illnesses, claiming that there were irrelevant to proving the fraud and FDCA violations. In rejecting this argument, the district court held "[t]he evidence of salmonella illnesses

is admissible as both direct evidence and as intrinsic evidence.” Id. at 1307. The district court found that the evidence of salmonella illnesses from around the country were admissible to prove that the peanuts were in fact adulterated (i.e., contaminated) and shipped in interstate commerce.

Id. The district court further held:

In addition, evidence of salmonella illnesses is inextricably intertwined with the crimes indicted in this case. The salmonella outbreak and ensuing illnesses provides context to the offenses and explains how and why government agencies began the investigation that led to PCA and the defendants. Without that information, the jury would be invited to speculate about the background to the prosecution.

Id.; see also id. at 1308 (“In addition to serving as direct evidence, the evidence of salmonella illnesses completes the overall narrative in this case by illustrating the context and background for the investigation.”). Therefore, the district court denied the defendants’ motion to exclude.

Similar to the Parnell case, the nationwide fungal meningitis outbreak that began in September 2012 is both direct and intrinsic evidence in this case. Evidence of the fungal meningitis outbreak directly proves beyond any doubt that NECC’s MPA, which was shipped to twenty-three states, was in fact contaminated, and NECC’s representations about the quality of its drugs and compounding process was utterly false, misleading, and material. Evidence of the patients harmed by NECC’s contaminated drugs demonstrates the material significance of falsely marketing NECC’s drugs as sterile and USP-797 compliant, when they were not. The evidence will also demonstrate that the other pharmacist-conspirators working inside NECC’s clean room employed the same unsafe production practices in the compounding of their drugs as Chin did in compounding the MPA, and authorized the shipments of hundreds of lots of substandard drugs based on the same false representations.

Moreover, the evidence of the nationwide fungal meningitis outbreak is inextricably intertwined with the crimes charged in this case. As this Court knows, as a direct result of the outbreak, the Centers for Disease Control and Prevention (“CDC”) and the Food and Drug Administration (“FDA”) conducted a searching investigation of NECC, its clean rooms, and its drugs, and uncovered the numerous unsafe production practices and insanitary conditions that form the heart of the racketeering, mail fraud, and FDCA violations with which the remaining defendants are now charged. The context for why NECC was shut down, why the CDC and the FDA were investigating NECC, and what they were looking for is a crucial part of the overall narrative of this case. It is what happened. See United States v. Morales-Aldahondo, 524 F.3d 115, 120 (1st Cir. 2008) (“The court is not required to scrub the trial clean of all evidence that may have an emotional impact, where the evidence is part of the Government’s narrative.”).

Evidence of the outbreak that forced the defendants to cease their fraudulent operations will not be unfairly prejudicial. As stated above, the government does not intend to introduce evidence of autopsies (photos and medical examiner testimony) or testimonies of next-of-kin. Instead, the government intends to introduce evidence of the contaminated MPA, and the resulting fungal meningitis outbreak. This evidence will be presented through witnesses from the CDC and the FDA, as well as NECC customers, rather than the patients actually harmed by the drugs. See United States v. Caputo, 374 F. Supp. 2d 632, 640 (N.D. Ill. 2005) (“Allowing doctors to inform the jury regarding the nature and extent of the injuries will allow the Government to introduce those facts without the undue risk of prejudice attendant to the patients’ testimony.”). The government has voluntarily taken these steps to ensure that the evidence will not inflame the passions of the jury, but rather to present the truth of what occurred at NECC in a straightforward and efficient manner. The government should not be forced to try the remaining defendants based

on counterfactual scenarios, untethered to reality. See United States v. McRae, 593 F.2d 700, 707 (5th Cir. 1979) (“Unless trials are to be conducted on scenarios, on unreal facts tailored and sanitized for the occasion, the application of Rule 403 must be cautious and sparing.”); Wagenmann v. Adams, 829 F.2d 196, 217 (1st Cir. 1979) (“A controlled environment for the reception of proof is essential, but an artificially sterile environment is neither necessary nor desirable.”).

Accordingly, because evidence of the fungal meningitis outbreak caused by the contaminated MPA is highly probative and admissible as to the charges against these defendants, the government submits that the Motion should be denied.

### **CONCLUSION**

For all the above reasons, the United States respectfully requests that the Court deny the Motion.

Respectfully submitted,

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Dated: April 10, 2018

Certificate of Service

I hereby certify that the foregoing documents filed through the ECF system will be sent electronically to counsel for the defendant, who is a registered participant as identified on the Notice of Electronic Filing (NEF).

By: /s/ George P. Varghese  
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Dated: April 10, 2018